## AMENDMENTS TO THE CLAIMS

Please replace all prior versions and listings of claims with the following listing of claims.

1. ***(Currently Amended)*** A system for managing clinical trials, the system comprising:

at least one database for storing information relating to at least one clinical trial; and

one or more processors configured to:

~~a Web client, wherein the Web client can access the Web via a Web browser;~~

~~a client;~~

~~a server, wherein the Web client can access the server via a Web connection and the client can access the server via a connection other than the Web connection; and~~

~~a patient records database,~~

interface with one or more client devices of one or more users, at least one of the one or more users having an assigned role in the at least one clinical trial,

receive, from a user, protocol design information relating to design of a protocol for the at least one clinical trial,

interface with one or more third party standards databases to acquire predefined standards information relevant to the protocol for the at least one clinical trial,

formulate the protocol using at least the design information and the standards information,

store the formulated protocol in the at least one database,

receive subject information relating to one or more subjects of the at least one clinical trial,

store the subject information in the at least one database,

receive clinical data regarding the one or more subjects relevant to the at least one clinical trial,

store the clinical data in the at least one database,

formulate at least one clinical result based on at least the protocol, the subject data, and the clinical data,

store the at least one clinical result in the at least one database, and

provide information stored in the at least one database to one or more of the one or more users via the one or more client devices, wherein access for a given user from the one or more users is gated based on the given user's assigned role

~~wherein the patient records database can be accessed by the server and the patient records database is logically partitioned and distributed based on a role in the clinical trials process of a user accessing the information~~.

2. ***(Currently Amended)*** The system of claim **1**, wherein the one or more client devices include a Web client that interfaces with the one or more processors via a Web connection, the Web client comprising ~~comprises~~ one ~~or more~~ of a computer, a cellular telephone, [[and]] or a personal data assistant.

3. ***(Currently Amended)*** The system of claim **1**, wherein the one or more client devices include at least one client device that interfaces with the one or more processors via a connection other than the Web connection, the at least one client device comprising ~~comprises~~ one ~~or more~~ of a computer, a cellular telephone, [[and]] or a personal data assistant.

4. ***(Currently Amended)*** The system of claim **1**, wherein the one or more users include one or more of ~~user comprises one of~~ a sponsor, a regulator, an investigator, a site, a patient, [[and]] or a monitor.

5. ***(Currently Amended)*** The system of claim **1**, wherein the one or more processors are further configured to ~~server provides applications one or more of comprising~~:

~~a trial design application, wherein the trial design application allows a clinical trial to be designed, developed, and customized;~~

~~a trial conduct application, wherein the trial conduct application manages ongoing operations of the clinical trial;~~

~~a trial monitoring application, wherein the trial monitoring application provides information about the ongoing operations of the clinical trial at a moment in time during the clinical trial;~~

~~a trial analysis application, wherein the trial analysis application provides information about the results of the clinical trial up to the time the trial analysis application is accessed~~;

~~a trial closure application, wherein the trial closure application performs a function to closeout the clinical trial;~~

~~a portal application, wherein the portal application provides a user interface accessible through the Web connection;~~

~~a commercial off the shelf software application, wherein the commercial off the shelf software application integrates external software used by the system;~~

compare received clinical data with one or more predefined ~~a good clinical information application, wherein the good clinical information application assures that collected data is compliant with industry regulations and standards, is in accordance with an organizational workflow and the clinical trial critical path, adheres to~~
data integrity standards, wherein all information stored in the at least one database is stored according to one or more predefined ~~and is maintained in accordance with~~ security and privacy standards,[[;]]

~~an applications interface application, wherein the applications interface application allows the client to access the system;~~ and

wherein the one or more processors configured to provide information stored in the at least one database to one or more of the one or more users via the one or more client devices further comprise one or more processors configured to provide ~~a security application, wherein the security application allows~~ user-defined password-protected access to the at least one database according to the predefined security and privacy standards ~~data and assures the~~

~~security and integrity of the data while maintaining the compatibility with industry standards and regulations~~.

6. ***(Currently Amended)*** The system of claim [[5]] 1, wherein the one or more processors are further configured to generate one or more reports for filing with a regulatory entity using at least the protocol, the subject data, the clinical data, and the at least one clinical result ~~comprising a trial submission application, wherein the trial submission application assembles information required for regulatory submissions and generates reports for regulatory reporting~~.

7. ***(Currently Amended)*** The system of claim 5, wherein the one or more predefined data integrity ~~industry~~ standards ~~and regulations comprise~~ include one or more of the Health Level 7, 21 CFR Part II, Health Insurance Portability and Accountability Act (1996), [[and]] or American Society for Testing and Materials requirements.

8. ***(Currently Amended)*** The system of claim [[5]] 1, wherein ~~the trial design application comprises a dictionary and standards component, wherein the dictionary and standards component enables interfaces between the system and relevant dictionaries and standards comprising~~ the one or more third party standards databases comprise one or more databases including one or more of common data elements, common toxicity criteria, MedDRA codes, ICD9/10 codes, IMT codes, [[and]] or Common Data Interchange Standards Consortium.

9. ***(Currently Amended)*** The system of claim [[7]]1, wherein the one or more processors are further configured to receive potential candidate information, compare the potential candidate information with candidate acceptance rules, and identify one or more of the one or more subjects based on the comparison ~~the trial design application further comprises a clinical development planner component, wherein the clinical development planner component assists in identification of clinical trial candidates for development and helps in creating target product profiles~~.

10. ***(Currently Amended)*** The system of claim [[7]]1, wherein the one or more processors are further configured to assign codes from a predetermined set of codes to one or more of diagnosis information, treatment information, disease information, or toxicity data present in the subject data, the clinical data, or the clinical results ~~the trial design application further comprises a protocol manager component, wherein the protocol manager component allows the definition of all elements of the clinical trial in a collaborative manner with tight document control~~.

11. ***(Currently Amended)*** The system of claim [[5]] 1, wherein the formulated protocol includes one or more controlled documents detailing implementation of the protocol and wherein the one or more processors are further configured to ~~trial conduct application comprises one or more of~~:

receive change information relating to a change in the formulated protocol,

modify one or more of the one or more controlled documents according to the change information ~~a change management system component, wherein the change management system component allows for the implementation of clinical quality assurance and control through the ability to revise, version, and track modifications and approvals on controlled documents comprising one or more of protocols, informed consents, case reports forms, investigative brochures, patient materials, and advertising and marketing materials;~~

~~a subject registration manager component, wherein the subject registration manager component registers patients and profiles them against clinical trial inclusion and exclusion criteria for appropriate patient recruitment, allows for the collection of demographic, payer, referring physician, and emergency information as one portion of the complete clinical trial related electronic medical record, and captures information about the referring physician for the purposes of evaluating investigative site performance, gathering patient population characteristics, and maintaining a two way flow of information pertaining to the patients medical condition and progress through the~~

~~trial;~~

~~a financial account manager component, wherein the financial account manager component enables gate keeping of medical billing to assure appropriate billing practices in the context of clinical research;~~

~~an investigation agent manager component, wherein the investigational agent manager component allows the capture of all drug distribution, tracking, disposition, accountability, transfer, and return in accordance with regulations and a clinical trial protocol;~~

~~a patient evaluation manager component, wherein the patient evaluation manager component facilitates interpretive summaries, diagnosis code assignment, and treatment code assignment to allow for assurance of compliance with the clinical trial protocol, proper study visit documentation, streamlined serious adverse event reporting, and clinical outcome evaluation;~~

~~a treatment regimen manager component, wherein the treatment regimen manager component allows for a standardized mechanism for treatment courses and dose escalations in accordance with algorithms that are configured in accordance with the clinical trial protocol;~~

~~a clinical data import manager component, wherein the clinical data import manager component allows interface with radiology imaging systems for import of radiographic data and diagnostic interpretations, medical information systems for import of medical data, and medical information systems for import of laboratory data for the clinical trial;~~

~~an auto encoding component, wherein the auto encoding component codes disease categories and toxicity data through access to current global libraries and coding algorithms; and~~

~~an adverse event manager component, wherein the adverse event manager component collects and tracks all adverse events in the clinical trial process~~.

12. ***(Currently Amended)*** The system of claim [[11]] 1, wherein the one or more processors are further configured to ~~the trial conduct application further comprises an encounter scheduler and tracker component, wherein the encounter scheduler and tracker component integrates the scheduling of~~ schedule one or more clinical trial-related visits for one or more subjects, ~~with routine physician office visits~~ and wherein the received clinical data includes information relating to the patient captured at the one or more scheduled ~~captures physician-patient encounter data from each~~ clinical trial-related visits ~~visit~~.

13. ***(Currently Amended)*** The system of claim [[5]] 1, wherein the clinical data includes adverse event data relating to one or more adverse events relevant to the at least one clinical trial, and wherein the one or more processors are further configured to generate one or more reports relating to the adverse event data in compliance with one or more predetermined adverse event reporting requirements ~~trial monitoring application comprises one or more of a database snapshot generator component, wherein the database snapshot generator component enables access to data for real-time clinical trial status monitoring at definable intervals for resource allocation, trend analysis, decision support, and interim analysis; and~~

~~a subject status manager component, wherein the subject status manager component ascertains the status of all subjects in the clinical trial and captures reasons subjects leave the clinical trial~~.

14. ***(Currently Amended)*** The system of claim [[12]] 1, wherein one or more processors are further configured to provide information from the at least one database to one or more entities to comply with one or more predetermined monitoring or auditing requirements ~~the trial monitoring application further comprises a monitor and auditor manager component, wherein the monitor and auditor manager component assures compliance with regulations requiring specific monitoring and auditing of the clinical trial process~~.

15. ***(Currently Amended)*** The system of claim [[12]] 1, wherein the one or more processors are further configured to generate one or more ~~trial monitoring application further comprises a case report form manager component, wherein the case report form manager component allows the design and tracking of paper and electronic~~ case report forms in one or more of paper or electronic form.

16. ***(Currently Amended)*** The system of claim [[5]] 1, wherein the one or more processors are further configured to generate ~~the trial analysis application comprises a clinical outcome manager component, wherein the clinical outcome manager component generates~~ interim and final clinical trial status reports.

17. ***(Currently Amended)*** The system of claim [[15]] 1, wherein the clinical data includes drug distribution information relating to drugs dispensed to one or more subjects participating in the at least one clinical trial and wherein the one or more processors are further configured to generate one or more reports reflecting part or all of the drug distribution information according to one or more predetermined drug distribution rules ~~trial analysis application further comprises an executive information manager component, wherein the executive information manager component allows for the monitoring of key executive vital signs, data analysis, and business intelligence~~.

18. ***(Currently Amended)*** The system of claim [[5]] 1, wherein the one or more processors are further configured to ~~the applications interface application comprises~~:

~~an application programming interface component, wherein the application programming interface component enables~~ enable external applications to communicate with the system; and

~~an XML Data Pump component, wherein the XML Data Pump component allows~~ facilitate import and export of data in XML format to and from the patient records database.

19. ***(Currently Amended)*** The system of claim 18, wherein the one or more processors configured to enable external applications to communicate with the system are further configured to allow ~~the applications interface application further comprises a mobile connectivity component, wherein the mobile connectivity component allows~~ mobile devices to enter and retrieve data from the at least one database as ~~the client~~ one of the one or more clients.

20. ***(Currently Amended)*** The system of claim 18, wherein the one or more processors are further configured to ~~applications interface application further comprises a patient records manager component, wherein the patient records manager component allows~~ receive information from external electronic medical records as clinical data ~~to be added to the clinical trials process, which provides the system with demographic information~~.

21. ***(Currently Amended)*** A computer-implemented method for reporting clinical trials information, the method being executed by one or more processors configured to perform one or more operations comprising:

~~creating~~ identifying one or more reporting requirements for a specific stakeholder associated with a clinical trial;

extracting data from ~~the system~~ at least one database related to the clinical trial based on the reporting requirements for the stakeholder;

validating the extracted data against one or more predefined regulations [[and]] or standards;

generating one or more clinical results using ~~creating information from~~ the extracted data based on ~~what is known about~~ a role associated with the specific stakeholder; and

displaying the information to the specific stakeholder.

22. ***(Currently Amended)*** The method of claim 21, wherein the role associated with the specific stakeholder comprises one of a sponsor, a regulator, an investigator, a site, a patient, [[and]] or a monitor.

23. ***(Currently Amended)*** A computer-implemented method for monitoring events ~~within a system for managing~~ during clinical trials, the method being executed by one or more processors configured to perform a plurality of operations comprising:

receiving event information relating to performance of an event defined in a protocol of a clinical trial ~~performing an event in a clinical trials protocol~~;

validating the event information using one or more predefined standards ~~checking the event against business logic rules, industry regulations, and industry standards; and~~

determining, according to one or more predefined alert rules, whether at least one stakeholder associated with the clinical trial is to be alerted of the event; and

alerting the at least one stakeholder of the event.

24. ***(Currently Amended)*** A computer-implemented method for scheduling and tracking appointments of a clinical trial subject, the method being executed by one or more processors configured to perform a plurality of operations comprising:

enrolling one or more subjects in a clinical trial based on inclusion and exclusion criteria of a protocol of the clinical trial;

generating ~~designing~~ a schedule of subject visits for at least one of the one or more enrolled subjects based on ~~a clinical trial~~ the protocol;

~~enrolling a subject based on inclusion and exclusion criteria of the clinical trial protocol;~~

~~scheduling subsequent visits for the subject;~~

providing one or more alerts ~~that the enrolled subject should be sent~~ regarding reminders to be sent to the at least one subject in advance of ~~subsequent visits of the~~ scheduled subject visits;

generating a checklist of items related to a scheduled visit of the at least one subject ~~upon a visit by the subject~~;

documenting ~~the checklist of~~ items from the checklist that are completed ~~and~~ or not completed ~~after the visit by the subject~~;

documenting ~~cancelled and missed~~ scheduled visits not attended by the at least one subject;

dropping the at least one subject from the clinical trial if a number of visits ~~cancelled and missed~~ not attended exceeds a predetermined threshold; and

notifying the at least one subject when the number of visits ~~cancelled and missed~~ not attended exceeds the predetermined threshold~~; and~~

~~documenting the dropping of the subject when the number of visits cancelled and missed exceeds the threshold~~.

25. ***(Currently Amended)*** The method of claim 24, wherein the ~~subsequent~~ scheduled subject visits comprise one or more of an office visit, laboratory tests, ~~x-ray~~ imaging tests, procedures, [[and]] or preparation for procedures.

26. ***(Currently Amended)*** The method of claim 24, wherein the checklist of items include ~~comprises~~ one or more of prompting a principal investigator review and signature, generating patient instructions, generating a coordinator checklist, checking laboratory results, checking pathology results, checking microbiology results, [[and]] or checking study reports.

27. ***(Currently Amended)*** The method of claim 24, wherein the predetermined threshold of visits ~~cancelled and missed~~ not attended comprises three visits.

28. ***(Currently Amended)*** The method of claim 24, wherein the notifying the at least one subject comprises sending a certified letter to the at least one subject.

29. ***(Currently Amended)*** A computer-implemented method for assuring good clinical information in scheduling and tracking the appointments of a clinical trial subject, the method being executed by one or more processors configured to perform a plurality of operations comprising:

receiving a protocol for a clinical trial;

formulating a schedule of visits for at least one subject enrolled in the clinical trial;

modifying the ~~checking a designed~~ schedule of subject visits ~~for consistency~~ to be consistent with [[a]] the clinical trial protocol and predefined rules of informed consent;

collecting subject information ~~in a manner compliant with industry regulations and~~ according to one or more predefined standards;

checking the collected subject information against inclusion and exclusion criteria of one or more predetermined business logic rules;

~~changing subject information coding to indicate enrolled and non-enrolled subjects;~~

~~checking lead time of a scheduled visit against all other scheduled visits for conflicts;~~

for at least one subject visit from the schedule of visits, sending a ~~assuring that~~ reminder to the at least one patient regarding the at least one subject visit ~~calls are made and documented~~;

dropping the at least one subject from the clinical trial if a number of visits not-attended exceeds a predetermined threshold ~~assuring that due diligence is shown and documented in regard to cancelled and missed visits by subjects~~;

~~assuring that proper methods are used to drop a subject from the clinical trial;~~

notifying the at least one subject when the number of visits not attended exceeds the predetermined threshold ~~assuring the proper notice is given to a dropped subject; and~~

~~assuring the subject information of a dropped subject is properly identified in the system~~.

30. ***(Currently Amended)*** A computer-implemented method for alerting and reporting in scheduling and tracking the appointments of a clinical trial subject, the method being executed by one or more processors configured to perform a plurality of operations comprising:

generating a schedule of subject visits for at least one subject enrolled in a clinical trial ~~subject instructions at time of scheduling a subject visit~~;

~~generating a checklist automatically at beginning of the subject visit;~~

notifying, at a beginning of at least one subject visit from the generated schedule of subject visits, at least one stakeholder associated with the clinical trial that the at least one subject visit has begun ~~at the beginning of the subject visit~~;

if the at least one subject has failed to attend at least one subject visit from the generated schedule of subject visits, alerting the at least one stakeholder that the at least one subject has not attended the at least one subject visit ~~if a scheduled visit is missed or cancelled~~;

~~alerting at least one stakeholder before a scheduled subject visit;~~

~~generating a checklist to track proper compliance with follow-up procedures~~; and

dropping the at least one subject from the clinical trial if a number of visits not-attended exceeds a predetermined threshold;

~~alerting~~ notifying the at least one stakeholder if the at least one subject is dropped for exceeding [[a]] the predetermined threshold ~~of missed and cancelled visits~~.

31. ***(Currently Amended)*** The method of claim [[29]]30, wherein the stakeholder comprises one of sponsor, regulator, investigator, site, patient, [[and]] or monitor.

32 - 37. ***(Cancelled)***

38. ***(Currently Amended)*** A computer-implemented method for closing-out a clinical trial, the method being executed by one or more processors configured to perform a plurality of operations comprising:

~~providing a first report of treatment allocation for all enrolled subjects;~~

~~providing a second report on all used and unused investigational products;~~

locking a ~~clinical trial~~ database storing information regarding the clinical trial after ~~completion of~~ all information regarding subjects enrolled in the clinical trial has been entered ~~case report forms~~;

~~performing a final analysis on the locked clinical trial database;~~

notifying at least one stakeholder associated with the clinical trial of completion of the clinical trial when the database has been locked; and

generating ~~drafting~~ a final clinical study report using the information stored in the database.

39 - 47. ***(Cancelled)***